DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 5-6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (previously cited) in view of Schmidt et al. (US Patent No. 4,925,670), McGinity et al. (previously cited), Chavannes (previously cited), Goldsworthy et al. (previously cited), and Barth (previously cited).

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer, colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). Envisioned polymers include alkyl ethers of celluloses and gelatin (see column 4 lines 8-10 and 17). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient

containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film from solution (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process or all the other known casting processes that are suggested.

Schmidt et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with medicinal agents, a plasticizer and optionally flavorings and dyes (see column 1 lines 11-16, column 2 lines 14-18, column 3 lines 24-34 and 41-44). The envisioned polymers include gelatin and celluloses as Suzuki et al. also teach (see column 27-31). Schmidt et al. teach that an aqueous coating solution is applied via synchronized rollers to the carrier web after the solution is heated to 60ºC to 80ºC (see column 3 lines 55-62 and column 4 lines 47-53; instant claims 5a and 6a).

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or from one reel to another, between two rollers where one contains the film-forming solution on its surface (see column 3 lines 21-34, column 4 line 64-column 5 line 19; instant claims 5b and 6b and 9-10). One of the rollers grips/guides the carrier while turns cooperatively due to the movement of the carrier and

applies the film-forming solution; thereby qualifying as synchronized rollers (see elements 31 and 30 in figure 7; instant claim 5b and 6b). The carrier is envisioned as a metal or paper (see column 3 lines 23-34; instant claim 3). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claims 5c and 6c). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and column 6 lines 52-56; instant claims 5d and 6d). The carrier then passes through a buffing brush to clean the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61).

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claims 5di and 6di). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Barth teaches subjecting sheets of material on a continuous belt to a thermal treatment in a drying oven where the gaseous material removed from the sheets do not

escape to the atmosphere (column 1 lines 57-64; instant claims 5ei and 6ei). Heated gas is introduced into a chamber through which the sheets travel (interpreted as a thermal treatment) (see figure 1 and column 2 lines 49-53). This treatment liberates material such as solvent and medicine residue which are carried by the gas (see column 3 lines 49-50). This refuse gas is collected by a withdrawal line that is connected to a vacuum pump that removes this gas from the drying chamber to avert its entry into the atmosphere (see column 5 lines 58-67). The vacuum controls the circulation of the air by guiding it out of the drying chamber (controlled air circulation) (see instant claims 5eii and 6eii). Barth goes on to teach that the gas collected by the withdrawal line is fed to an afterburner (see column 3 lines 51-54; instant claims 5eii and 6eii).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes with an endless belt or reel based process to prepare the medicinal films of Suzuki et al. with lettering printed on the films themselves due to 1) the suggestion by Suzuki et al. to utilize an endless belt type film or other film casting methods known in the art and 2) the suggestion of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Given that both celluloses and gelatin were envisioned as polymers in the film of Suzuki et al. and the teachings of Schmidt et al. to heat such a gelatin containing solution prior to casting, it also would have been obvious to heat the coating solution to 60ºC to 80ºC as taught because this was a routine method of preparing a polymer casting solution that was known to contain gelatin. Additionally, it also would have been obvious to modify this method of Chavannes based on the teachings of Goldsworthy et al. who provide

mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning a belt utilized in a coating/casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of Suzuki et al. in view of Chavannes and McGinity et al., instead of the taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier employed in this method would become contaminated with material from the coating solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claims 5d-5di and 6d-6di). Since Barth teaches an apparatus that provides a thermal treatment to a continuous belt or sheet of material that removes material from its surface, it would also have been to one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal treatment for the method of Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., and Goldsworthy as a the use of a known technique to improve a similar product in the same way (e.g. removal of undesired components from sheets of product with heat).

While the cited references are silent regarding all the mechanisms by which the materials from the cast film contaminate the carrier, they recognize the need to remove residual materials prior to the reuse of the carrier. In addition, all cast components will have a diffusion coefficient in the carrier that will increase as a result of the elevated temperature due to thermal treatment as taught by Goldsworthy et al. A thermal treatment that is sufficient to remove residual materials as taught by Goldsworthy et al. will also remove material that has diffused into the carrier due to the increased rate of diffusion it elicits. Applicants teach that components of the coating will penetrate into the

carrier material by diffusion and result in contamination of this carrier when cast onto its surface and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Since the method of Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., and Barth renders obvious the method steps instantly claimed, their teachings result in a cleaned carrier being reused in a film casting process and also necessarily result in the removal of diffusion contamination from the carrier.

The instant claims recite a method of cleaning a carrier that has been previously utilized as a casting substrate for an active-agent containing film. Numerous methods of casting a film were known in the art at the time of the invention and are suggested for use by Suzuki et al. In addition, the need to clean the casting substrate prior to its reuse in the film casting process was also recognized at the time of the invention as indicated by Chavannes. Methods of cleaning a substrate were known as was the need to dispose of the waste product removed from the substrate and both Goldsworthy et al. and Barth attest to this fact. Therefore claims 3, 5-6, and 9-10 are obvious over Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., and Barth.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., and Barth as applied to claims 3, 5-6, and 9-10 above, and further in view of Lerdkanchanaporn et al. (previously cited) and Lerdkanchanaporn et al. (previously cited - henceforth Lerdkanchanaporn B).

Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., and Barth make obvious the method for removing contaminating substances from a carrier material comprising: a) heating an active-ingredient-containing drug, food or cosmetic coating to approximately 40 to 100ºC, b) coating the heated active-ingredient-containing drug, food or cosmetic coating onto a neutralized carrier material [Applicants teach that neutralization occurs when a carrier is made to be essentially free of contaminants from a coating that was previously applied and removed (see instant specification page 4 lines 16-19). Therefore the cleaned carrier of Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy, and Barth that is fed back to the coating process is a neutralized carrier] via synchronized rollers, substances within said coating diffusing into and thereby contaminating said carrier material with drug, food or cosmetic contaminating substances, c) drying the coated carrier material to form an active-ingredient-containing or cosmetic film, d) peeling the dried active-ingredient-containing film off the contaminated carrier material and e) subjecting the contaminated carrier material to a thermal treatment which comprises i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from the carrier material to form neutralized carrier material, and ii) feeding the removed contaminants or other undesired substances to a thermal after- burning using controlled air circulation, and f) providing the neutralized carrier material to said coating step. Within the highlighted teachings, this modified reference provides for a paper carrier on a reel (e.g. instant claim 1f), the drying apparatus of Barth forms a tunnel through which the contaminated carrier would travel, therefore qualifying as a

drying tunnel (see figure 1; instant claim 7), and the reuse of the carrier in the coating process after it has been cleaned (see instant claims 1f and 7). Additionally, since Suzuki et al. teach ibuprofen as a drug envisioned in their film, this modified reference also renders this decontamination method obvious when the coated film contains ibuprofen (see column 4 lines 33-36 and 56). The modified reference does not explicitly teach the temperature at which the cleaning thermal treatment occurs or the time over which the treatment is applied.

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75ºC -77ºC under atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen at a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77ºC which corresponds to approximately 4.22×10^{-5} mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., and Barth clearly envision the contamination of the carrier with material from the film that has been removed. Both one of ordinary skill in the art and the instant inventors would expect that traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77ºC, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term

"about" that defines it otherwise. While Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., Barth, and Lerdkanchanaporn et al. do not explicitly teach the time for the removal of essentially all the undesired substances, the approximate rate of ibuprofen evaporation per area (e.g. coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. Thus claims 1 and 7 are obvious over Suzuki et al. in view of Chavannes, Schmidt et al., McGinity et al., Goldsworthy et al., Barth, Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of Schmidt et al., McGinity et al., Chavannes, Goldsworthy et al.(previously cited), Dieudonne et al. (previously cited), Wimberger et al. (previously cited), Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer, colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). Envisioned polymers include alkyl ethers of celluloses and gelatin (see column 4 lines 8-10 and 17). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient

containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film from solution (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process or all the other known casting processes that are suggested.

Schmidt et al. teach oral pharmaceutical film that includes a water-soluble polymer along with medicinal agents, a plasticizer and optionally flavorings and dyes (see column 1 lines 11-16, column 2 lines 14-18, column 3 lines 24-34 and 41-44). The envisioned polymers include gelatin and celluloses as Suzuki et al. also teach (see column 27-31). Schmidt et al. teach that an aqueous coating solution is applied via synchronized rollers to the carrier web after the solution is heated to 60ºC to 80ºC (see column 3 lines 55-62 and column 4 lines 47-53; instant claim 1a).

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or from one reel to another, between two rollers where one contains the film-forming solution on its surface (see column 3 lines 21-34, column 4 line 64-column 5 line 19; instant claim 1b). One of the rollers grips/guides the carrier while turns cooperatively due to the movement of the carrier and applies the film-

forming solution; thereby qualifying as synchronized rollers (see elements 31 and 30 in figure 7; instant claim 1b). The carrier is envisioned as a metal or paper (see column 3 lines 23-34; instant claim 1e). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claim 1c). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and column 6 lines 52-56; instant claim 1d). The carrier then passes through a buffing brush to clean the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61).

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claim 1di). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Dieudonne et al. teach an infrared radiator in a continuous oven as a means of applying a thermal treatment to thin plate-like components (see abstract and column 1 lines 4-8)

Wimberger et al. teach a process where a paper web (carrier) is passed through a thermal treatment zone such that a surface contaminant (solvent) is removed via a thermal treatment and fed to an afterburner via a fan (controlled air circulation) (see column 1 lines 50-59, column 2 lines 66-68; instant claims 1 and 3).

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75ºC -77ºC under atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77ºC which corresponds to approximately 4.22×10^{-5} mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes with an endless belt or reel based process to prepare the medicinal films of Suzuki et al. due to the suggestion by Suzuki et al. to utilize an endless belt type film or other film casting methods known in the art and that of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Given that both celluloses and gelatin were envisioned as polymers in the film of Suzuki et al. and the teachings of Schmidt et al. to heat such a gelatin containing solution prior to casting, it also would have been obvious to heat the coating solution to 60ºC to 80ºC as taught. Additionally, it also would have been obvious to modify this

method based on the teachings of Goldsworthy et al. who provide mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning a belt utilized in a coating/casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of Suzuki et al. in view of Chavannes and McGinity et al., instead of the taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier employed in this method would become contaminated with material from the coating solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claim 1d-1di). Since Dieudonne et al. teaches an apparatus that provides a thermal treatment to a continuous belt of plate-like material, it would also have been one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal treatment for the method of Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., and Goldsworthy as a simple substitution of one known equivalent element for another (e.g. general thermal treatment device for infrared thermal treatment device). This thermal cleaning treatment would necessarily liberate gaseous waste; therefore it also would have been obvious to feed this material to an afterburner as taught by Wimberger et al. as the application of a known technique to a similar method ready for improvement to yield a predictable result.

Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. clearly envision the contamination of the carrier with material from the film that has been removed as well as ibuprofen as a component of the film. Both one of ordinary skill in the art and the instant inventors

would expect that traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77ºC, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term "about" that defines it otherwise. Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. do not explicitly teach the time for the removal of essentially all of the undesired substances, the approximate rate of ibuprofen evaporation per area (coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. While the cited references are silent regarding all the mechanisms by which the materials from the cast film contaminate the carrier, they recognize the need to remove residual materials prior to the reuse of the carrier. In addition, all cast components will have a diffusion coefficient in the carrier that will increase as a result of the elevated temperature due to thermal treatment as taught by Goldsworthy et al. A thermal treatment that is sufficient to remove residual materials as taught by Goldsworthy et al. will also remove material that has diffused into the carrier due to the increased rate of diffusion it elicits. Applicants teach that components of the coating will penetrate into the carrier material

by diffusion and result in contamination of this carrier when cast onto its surface and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Since the method of Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. renders obvious the method steps instantly claimed, their teachings result in a cleaned carrier being reused in a film casting process and also necessarily result in the removal of diffusion contamination from the carrier.

The instant claims recite a method of cleaning a carrier that has been previously utilized as a casting substrate for an active-agent containing film. Numerous methods of casting a film were known in the art at the time of the invention and are suggested for use by Suzuki et al. In addition, the need to clean the casting substrate prior to its reuse in the film casting process was also recognized at the time of the invention as indicated by Chavannes. Methods of cleaning a substrate were known as was the need to dispose of the waste product removed from the substrate and Goldsworthy et al. along with Dieudonne et al. and Wimberger et al. attest to this fact. Details regarding the conditions under which this cleaning process is conducted depend upon the contaminating material and therefore require selection of an appropriate temperature/pressure/solvent to liberate the undesired material; the Lerdkanchanaporn references highlight that this basic information was also known to the artisan of ordinary skill. Thus claims 1 and 8 are obvious over Suzuki et al. in view of Schmidt et al., Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., Wimberger et al., Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Response to Arguments

Applicants' arguments submitted May 4, 2011, have been fully considered. While new grounds of rejection are presented to address the new limitation of heating the coating to a particular temperature, all of the previously cited references are still relied upon in these rejections.

Applicants argue that there would have been no motivation to incorporate an additional thermal treatment. Chavannes demonstrates the recognized need to clean a carrier web used for film casting before its reuse. Goldsworthy et al. teach functionally equivalent methods of cleaning a carrier belt that is soiled with residual material that was previously cast on its surface which include both mechanical and thermal cleaning methods. Substitution of any one of these known methods for cleaning the carrier web of Chavannes for one another would have been obvious because they all achieve the same result. Applicants have not shown that anything unexpected results the use of a thermal cleaning methodology as compared to a mechanical or solvent based cleaning method. Thus the inclusion of an "additional thermal treatment" would have been obvious to the artisan of ordinary skill.

In addition, applicants argue that the cited references do not recognize the removal of contaminants that have diffused into a carrier as an issue. Prior art clearly details the recognition of the need to clean residual components left from coating materials cast onto the surface of carrier webs prior to their reuse as carriers (see Goldsworthy et al. column 2 lines 43-47 and Chavannes column 6 lines 57-61). Chavannes references US Patent application No. 635,982 which corresponds to Patent

No. 2,575,046 for details regarding the surface smoothing coating on the paper carrier web he employs (see column 3 lines 31-41). Polyvinyl alcohol is taught as the coating material which is known as a drug delivery matrix for ibuprofen and a host of other drugs (see Chavannes et al. US Patent No. 2,575,046 column 4 lines 8-16 and Ventouras US Patent No. 6,183,775 column 1 lines 51-59, column 2 lines 48-52, and column 3 lines 5-8, 21-22). Diffusion is a well-known thermodynamic phenomenon that generally occurs due to a concentration gradient and a film casting process by its very nature creates a concentration gradient between the casting coating and the carrier web which is initially devoid of ingredients from the coating. As a result of polyvinyl alcohol being well known to support the diffusion of a host of drugs for delivery, the artisan of ordinary skill in the art would expect some degree of diffusion of drug from the film coating solution into this coating layer on the paper web. Regardless of the mechanism responsible for locating the contaminants in or on the carrier, the detriment posed by residual coating materials to inter-batch consistency was known and recognized at the time of the invention. Since thermal treatment was a known methodology for removing residual materials from carrier webs, there was motivation for the artisan of ordinary skill to apply such a method to clean a carrier web prior to its reuse in a coating process line. A thermal treatment that is sufficient to remove material from a carrier in general will also remove material that has diffused into its surface by virtue of the increased diffusion coefficient of the material and the resulting increase in its rate of diffusion.

Applicants provide a series of truncated summaries of the references that were cited where each omits teachings from the references that were relied upon in the rejections as well as teachings that appear across multiple references. They then argue

that each reference does not teach the application of a heated coating onto a carrier with synchronized rollers. While not described with this terminology, Chavannes teaches the application of coating with synchronized rollers as noted in the new grounds of rejection above. A new reference has been cited to address the limitations regarding the coating temperature.

In response to applicant's argument that Suzuki et al., Chavannes, McGinity et al., Goldsworthy et al. and Barth are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The art of focus in the cited references is not divergent as applicants argue. Suzuki et al. teaches oral pharmaceutical film that can be prepared by a number of methodologies including casting while McGinty et al. teaches of the desire to apply markings or designs to the surface of pharmaceutical films. Chavannes teaches methods of casting films and applying markings to their surface where the carrier belt utilized requires cleaning between runs. Goldsworthy et al. teaches methods of cleaning a carrier belt between runs where a thermal treatment is envisioned. The necessity of cleaning production equipment between uses is well known in a host of arts and certainly is not limited to the process lines utilized in the production of foam insulation as suggested by applicants. Barth teaches a method of applying a thermal treatment to a belt where liberated solvent and drug are burned so as to avoid environmental contamination. Use of a known technique to improve a similar device in the same way (e.g. cleaning a belt

utilized in a coating line or burning of volatilized drug to avoid contamination of the environment) or simple substitution of one known element for another (thermal cleaning of a belt vs. mechanical cleaning of a belt) are valid reasons for the combination of these references as highlighted in the rejections. These points of connectivity facilitate the combination of these references in to the *prima facie* case of obviousness that is presented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634